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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	
BENJAMIN GASTON, et al.	Group Art Unit: 1614
Patent Application No. 10/380,763	Examiner: R.J. Hendley III
Filed: March 24, 2003	
For: THERAPEUTIC USE OF AEROSOLIZED S-NITROSOGLUTATHIONE IN CYSTIC FIBROSIS	

DECLARATION UNDER 37 C.F.R. 1.132

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

JONATHAN S. STAMLER and BENJAMIN GASTON hereby declare:

1. We are the inventors in the above-identified patent application.

2. Benjamin Gaston has an M.D. degree and is an Associate Professor of Pediatrics at the University of Virginia (Charlottesville). He trained at Brigham Women's Hospital (Harvard Medical School). He is a practicing pulmonologist. He is an expert in cystic fibrosis and pulmonary medicine.

3. Dr. Gaston is involved in an ongoing clinical investigation where aerosolized S-nitrosoglutathione in administered to patients with cystic fibrosis.

4. Jonathan Stamler has an M.D. degree and is a Professor of Medicine and Biochemistry at Duke University. He is also an Associate Investigator of the Howard Hughes Medical Institute at the Duke University Medical Center in Durham, North Carolina. He is a practicing cardiologist

and pulmonologist. He is co-author of a book titled "Methods in Nitric Oxide Research", John Wiley & Sons, New York, 1996.

5. Cystic fibrosis is not associated with vasoconstriction or constriction of corpus cavernosum.

6. Cystic fibrosis is not known to be induced by the increased metabolism of cGMP.

7. Increased levels of cGMP are not known to be beneficial for amelioration of cystic fibrosis symptoms.

8. Endogenous levels of EDRF relate to vascular function and not to symptoms of cystic fibrosis.

9. We are familiar with Garvey et al U.S. Patent No. 6,331,541 B1. Garvey et al administers phosphodiesterase inhibitor to block the breakdown of cGMP. Garvey et al administers NO donor to increase the amount of cGMP present by reacting NO with heme of guanylate cyclase. The point in Garvey et al is to provide an increased level of cGMP to relax blood vessels or corpus cavernosum.

10. In view of the point in Garvey et al being to increase level of cGMP and in view of cystic fibrosis not being induced by the increased metabolism of cGMP or having symptoms related to endogenous levels of EDRF, one skilled in the art would not believe Garvey's method would be beneficial in the treatment of cystic fibrosis even though Garvey lists cystic fibrosis as one of the disorders induced by metabolism of cGMP.

11. We further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are

punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date	Benjamin Gaston
9/9/03 Date	Jonathan S. Stamler